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PATENT
P-4423

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): D.J. Wright et al.

SERIAL NO.: 09/335,218 GROUP: 1655

FILING DATE: June 17, 1999 EXAMINER: B. Forman

FOR: METHOD AND OLIGONUCLEOTIDES FOR DETECTING NUCLEIC ACID SEQUENCE VARIATIONS

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231

ON: June 22, 2004
(DATE OF DEPOSIT)

BY: Donna M. Baumann
(NAME OF DEPOSITER)

Donna M Baumann 6-22-04
(SIGNATURE) (DATE)

Mail Stop PETITION
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RENEWED PETITION UNDER 37 C.F.R. § 1.137(b)

Sir:

Applicant submitted a Petition for Revival under 37 CFR8 1.137(b) on March 16, 2004. Applicant's Petition was denied in a decision mailed May 11, 2004 on the grounds that Applicant's petition lacked the required reply to an Office Action. Applicant hereby requests reconsideration of such decision.

Applicant respectfully submits that the required reply to an Office Action was filed on March 16, 2004. A copy of such reply is submitted herewith. A copy of a postcard, stamped by the USPTO, confirming receipt of such reply is attached hereto.

Accordingly, Applicant respectfully submits that there was no outstanding requirement. Applicant respectfully requests revival of the present application.

Respectfully submitted,

Dated: June 15, 2004

By: _____

Allan M. Kiang
Attorney for Applicant(s)
Reg. No. 42,725
(201) 847-7111

#79155

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P-4423

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ON: 3-16-04
(DATE OF DEPOSIT)

BY: Donna M. Baumann
(NAME OF DEPOSITER)

Donna M Baumann 3-16-04
(SIGNATURE) (DATE)

PETITION FOR REVIVAL UNDER C.F.R. § 1.137(b) OF APPLICATION FOR PATENT UNINTENTIONALLY ABANDONED

Sir:

The above-identified patent application became abandoned for failure to file a timely and proper rely to an Office Action dated July 08, 2003. Applicant respectfully submits that such failure was unintentional, and that the subsequent abandonment of the present application was likewise unintentional. Thus, applicant respectfully request revival of the present application.

APPLICANT PETITIONS FOR REVIVAL OF THIS APPLICATION

1. Applicant hereby authorizes the Commissioner to charge the amount of $1,300.00 for the Petition Fee required pursuant to 37 C.F.R. § 1.17(m) to Deposit Account No. 02-1666.

2. Filed herewith is a Reply to the above-noted Office Action.

3. Since this utility application was filed after June 8, 1995, no terminal disclaimer is required.

4. The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 C.F.R. § 1.37(b) was unintentional. Applicant's attorney inadvertently and unintentionally failed to file a timely and proper Reply to the Office Action. Therefore, the undersigned attorney respectfully submits that the application was unintentionally abandoned.

5. The Commissioner is hereby authorized to charge any additional fees for the filing of this Petition to the undersigned attorney's Deposit Account No. 02-1666 or credit the Deposit Account for any overpayment.

Respectfully submitted,

Dated: 15 March 2004

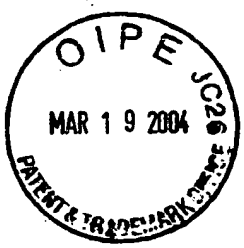
By: _____

Allan M. Kiang
Attorney for Applicant(s)
Reg. No. 42,725
(201) 847-7111

AMK

The Return of this post card, Properly stamped, will acknowledge receipt in the Patent & Trademark Office of the following:

1.-
2.- Response to OA of 3-3-04
3.- Petition for Revival
4.-
5.-



Docket No.: P-4423 Serial No.: 09 / 335,218

Filing Date: 6-17-99 Date Mailed: 3-16-04

Applicant(s) D. J. Wright et al Atty: AMK

Title: METHOD AND OLIGONUCLEOTIDES FOR DETECTING NUCLEIC ACID SEQUENCE VARIATIONS

Fee: 1,300.00 Charged to Deposit Account 02-1666

AMENDMENT TRANSMITTAL LETTER (Large Entity)	Docket No.
Applicant(s): D.J. Wright et al.	P-4423

Serial No.	Filing Date	Examiner	Group Art Unit
09/334,218	June 17, 1999	B. Forman	1655

Invention: METHOD AND OLIGONUCLEOTIDES FOR DETECTING NUCLEIC ACID SEQUENCE VARIATIONS

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST # PREV. PAID FOR		NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	32	-	32	=	0	x $18.00	$0.00
INDEP. CLAIMS	3	-	3	=	0	x $84.00	$0.00
Multiple Dependent Claims (check if applicable) ☐							$0.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT							$0.00

☒ No additional fee is required for amendment.

☐ Please charge Deposit Account No. in the amount of

☐ A check in the amount of to cover the filing fee is enclosed.

☒ The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666

- ☒ Any additional filing fees required under 37 C.F.R. 1.16.
- ☒ Any patent application processing fees under 37 CFR 1.17.

Signature

Dated: March 16, 2004

Allan M. Kiang
Attorney for Applicants
Reg. No. 42,735
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, New Jersey 07417

201-847-7111

cc:

I certify that this document and fee is being deposited on 3-16-04 with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Donna M. Baumann

Signature of Person Mailing Correspondence

Donna M. Baumann

Typed or Printed Name of Person Mailing Correspondence

PATENT
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The Assistant Commissioner of Patents
Washington, D.C. 20231

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ON: 3-16-04
(DATE OF DEPOSIT)

BY: Donna M. Baumann
(NAME OF DEPOSITER)

Donna M Baumann 3-16-04
(SIGNATURE) (DATE)

RESPONSE PURSUANT TO 37 CFR §1.111

Sir:

This paper is in response to the Official Action dated July 08, 2003.
Please consider the Amendments to the Claims beginning on page 2 of this paper.
Please consider the Remarks beginning on page 11 of this paper.

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A method for detecting a single nucleotide polymorphism in a target comprising, under isothermal conditions at about 37 degrees Celsius:

a) hybridizing a detector primer and a second primer to the target such that extension of the second primer by polymerase displaces the detector primer from the target sequence, wherein the detector primer comprises a diagnostic nucleotide for the single nucleotide polymorphism which is a 3' terminal nucleotide of the detector primer or about one to four nucleotides from the 3' terminal nucleotide of the detection primer;

b) extending the detector primer and the second primer with polymerase to produce a displaced detector primer extension product;

c) determining an efficiency of detector primer extension; and

d) detecting the presence or absence of the single nucleotide polymorphism based on the efficiency of detector primer extension.

2. (Original) The method of Claim 1 wherein the single nucleotide polymorphism is identified using the detector primer.

3. (Original) The method of Claim 2 wherein the single nucleotide polymorphism is identified using multiple detector primers, each comprising a different diagnostic nucleotide.

4. (Original) The method of Claim 3 wherein two detector primers are used to identify which of two possible alleles is present in the target sequence.

5. (Original) The method of Claim 3 wherein four detector primers are used to identify the nucleotide present in the target sequence at the position of the single nucleotide polymorphism.

6. (Original) The method of Claim 3 wherein each of the multiple detector primers has a different 5' tail sequence.

7. (Original) The method of Claim 1 wherein the detector primer further comprises a nucleotide which forms a nondiagnostic mismatch with the target sequence.

8. (Original) The method of Claim 7 wherein the nondiagnostic nucleotide is positioned within fifteen nucleotides of the diagnostic nucleotide in the detector primer.

9. (Original) The method of Claim 8 wherein the nondiagnostic nucleotide is positioned 1-5 nucleotides from the diagnostic nucleotide in the detector primer.

10. (Original) The method of Claim 9 wherein the nondiagnostic nucleotide is adjacent to the diagnostic nucleotide in the detector primer.

11. (Original) The method of Claim 7 wherein the detector primer is about 15-36 nucleotides long.

12. (Original) The method of Claim 11 wherein the detector primer is about 18-24 nucleotides long.

13. (Original) The method of Claim 1 wherein the second primer is an amplification primer.

14 (Previously Presented) The method of Claim 13 wherein the amplification reaction is selected from the group consisting of SDA, 3SR, NASBA, and TMA.

15. (Original) The method of Claim 1 wherein the detector primer is about 12-50 nucleotides long.

16. (Original) The method of Claim 15 wherein the detector primer is about 12-24 nucleotides long.

17. (Original) The method of Claim 16 wherein the detector primer is about 12-19 nucleotides long.

18. (Original) The method of Claim 1 wherein the presence or absence of the single nucleotide polymorphism is detected by means of a label associated with the detector primer.

19. (Original) The method of Claim 18 wherein the label becomes detectable upon extension of the detector primer or produces a change in signal upon extension of the detector primer.

20. (Previously Presented) The method of Claim 19 wherein the label is a fluorescent donor/quencher dye pair and an increase in donor dye fluorescence is detected as an indication of the presence of the single nucleotide polymorphism.

21. (Original) The method of Claim 19 wherein a change in fluorescence polarization is detected as an indication of the presence of the single nucleotide polymorphism.

22. (Original) The method of Claim 1 wherein a single nucleotide polymorphism in an HFE gene is detected.

23. (Original) The method of Claim 22 wherein the single nucleotide polymorphism is detected in exon 4 or exon 2 of the HFE gene.

24. (Original) The method of Claim 1 wherein the efficiency of detector primer extension is determined quantitatively.

25. (Withdrawn) A method for detecting a single nucleotide polymorphism in a target comprising, in an isothermal nucleic acid amplification reaction:

a) hybridizing a detector primer to the target, wherein the detector primer comprises a diagnostic nucleotide for the single nucleotide polymorphism about one to four nucleotides from a 3' terminal nucleotide of the detector primer which is complementary to the target sequence;

b) amplifying the target by hybridization and extension of the detector primer;

c) determining an efficiency of detector primer extension, and;

d) detecting the presence or absence of the single nucleotide polymorphism based on the efficiency of detector primer extension.

26. (Withdrawn) The method of Claim 25 wherein the single nucleotide polymorphism is identified using the detector primer.

27. (Withdrawn) The method of Claim 26 wherein the single nucleotide polymorphism is identified using two or more detector primers, each comprising a different diagnostic nucleotide.

28. (Withdrawn) The method of Claim 27 wherein two detector primers are used to identify which of two possible alleles is present in the target sequence.

29. (Withdrawn) The method of Claim 27 wherein four detector primers are used to identify the nucleotide present in the target sequence at the position of the single nucleotide polymorphism.

30. (Withdrawn) The method of Claim 27 wherein each of the multiple detector primers has a different 5' tail sequence.

31. (Withdrawn) The method of Claim 25 wherein the detector primer further comprises a nucleotide which forms a nondiagnostic mismatch with the target sequence.

32. (Withdrawn) The method of Claim 31 wherein the nondiagnostic nucleotide is positioned within fifteen nucleotides of the diagnostic nucleotide in the detector primer.

33. (Withdrawn) The method of Claim 32 wherein the nondiagnostic nucleotide is positioned 1-5 nucleotides from the diagnostic nucleotide in the detector primer.

34. (Withdrawn) The method of Claim 33 wherein the nondiagnostic nucleotide is adjacent to the diagnostic nucleotide in the detector primer.

35. (Withdrawn) The method of Claim 31 wherein the detector primer is about 15-36 nucleotides long.

36. (Withdrawn) The method of Claim 35 wherein the detector primer is about 18-24 nucleotides long.

37. (Withdrawn) The method of Claim 25 wherein the isothermal amplification reaction is selected from the group consisting of SDA, 3SR, NASBA and TMA.

38. (Withdrawn) The method of Claim 25 wherein the detector primer is about 12-50 nucleotides long.

39. (Withdrawn) The method of Claim 38 wherein the detector primer is about 12-24 nucleotides long.

40. (Withdrawn) The method of Claim 39 wherein the detector primer is about 12-19 nucleotides long.

41. (Withdrawn) The method of Claim 25 wherein the presence or absence of the single nucleotide polymorphism is detected by means of a label associated with the detector primer.

42. (Withdrawn) The method of Claim 41 wherein the label becomes detectable upon extension of the detector primer or produces a change in signal upon extension of the detector primer.

43. (Withdrawn) The method of Claim 42 wherein the label is a fluorescent donor/quencher dye pair and a decrease in donor dye fluorescence is detected as an indication of the presence of the single nucleotide polymorphism.

44. (Withdrawn) The method of Claim 42 wherein a change in fluorescence polarization is detected as an indication of the presence of the single nucleotide polymorphism.

45. (Withdrawn) The method of Claim 25 wherein the efficiency of detector primer extension is determined quantitatively.

46. (Withdrawn) An oligonucleotide which comprises:

a) a nucleotide sequence which hybridizes to an internal segment of a target nucleic acid downstream from a hybridization site for a primer such that extension of the primer displaces the oligonucleotide from the target sequence, and;

b) a 3' terminal nucleotide or a nucleotide about one to four nucleotides from the 3' terminal nucleotide which is diagnostic for a single nucleotide polymorphism which may be present in the target nucleic acid.

47. (Withdrawn) The oligonucleotide of Claim 46 wherein the diagnostic nucleotide is the 3' terminal nucleotide (N) or N-1.

48. (Withdrawn) The oligonucleotide of Claim 46 further comprising a nondiagnostic nucleotide within about one to fifteen nucleotides from the diagnostic nucleotide.

49. (Withdrawn) The oligonucleotide of Claim 48 wherein the nondiagnostic nucleotide is within about one to five nucleotides from the diagnostic nucleotide.

50. (Withdrawn) The oligonucleotide of Claim 49 wherein the diagnostic and nondiagnostic nucleotides, respectively, are selected from the group consisting of N and N-3, N-1 and N-2, and N-2 and N-3.

51. (Withdrawn) The oligonucleotide of Claim 46 which hybridizes downstream from an amplification primer for the target nucleic acid.

52. (Withdrawn) An oligonucleotide which is an amplification primer for an isothermal nucleic acid amplification reaction, the oligonucleotide comprising:

a) a 3' terminal nucleotide which is complementary to the target, and;

b) about one to four nucleotides from the 3' terminal nucleotide, a diagnostic nucleotide for a single nucleotide polymorphism which may be present in a target to be amplified.

53. (Withdrawn) The oligonucleotide of Claim 52 wherein the diagnostic nucleotide is at N-1 or N-2.

54. (Withdrawn) The method of Claim 25 further comprising, prior to amplifying, displacing the hybridized detector primer from the target by extension of an upstream primer.

55. (Currently Amended) A method for detecting a single nucleotide polymorphism in a target sequence comprising, <u>under isothermal conditions at about 37 degrees Celsius</u>:

a) hybridizing to the target sequence a detector primer comprising a diagnostic nucleotide for the single nucleotide polymorphism which is about one to four nucleotides from the 3' terminal nucleotide of the detection primer;

b) in a primer extension reaction, displacing the detector primer by extension of a second primer hybridized to the target sequence upstream of the detector primer, and;

c) detecting the presence or absence of the single nucleotide polymorphism based on an efficiency of detector primer extension.

56. (Previously Presented) The method of Claim 55 wherein the single nucleotide polymorphism is identified using the detector primer.

57. (Previously Presented) The method of Claim 56 wherein the single nucleotide polymorphism is identified using multiple detector primers, each detector primer comprising a different diagnostic nucleotide.

58. (Previously Presented) The method of Claim 57 wherein each of the multiple detector primers comprises a different 5' tail sequence.

59. (Previously Presented) The method of Claim 55 wherein the second primer is an amplification primer.

60. (Previously Presented) The method of Claim 55 wherein the detector primer comprises a label which becomes detectable upon extension of the detector primer or which produces a change in signal upon extension of the detector primer.

61. (Previously Presented) The method of Claim 60 wherein the label is a fluorescent donor/quencher dye pair and a decrease in donor dye fluorescence is detected as an indication of the presence or absence of the single nucleotide polymorphism.

62. (Cancelled)

63. (Currently Amended) A method for detecting a single nucleotide polymorphism in a target comprising, under isothermal conditions at about 37 degrees Celsius:

a) hybridizing a detector primer and a second primer to the target such that extension of the second primer by polymerase displaces the detector primer from the target sequence, wherein the detector primer comprises a diagnostic nucleotide for the single nucleotide polymorphism which is about two to four nucleotides from the 3' terminal nucleotide of the detection primer;

b) extending the detector primer and the second primer with polymerase to produce a displaced detector primer extension product;

c) determining an efficiency of detector primer extension, and;

d) detecting the presence or absence of the single nucleotide polymorphism based on the efficiency of detector primer extension.

REMARKS

Claims 1-24, 55-61 and 63 are in the present application.

Applicant respectfully thanks the Examiner for the telephonic interview conducted on March 01, 2004. Claims 1, 55 and 63 were discussed. Possible amendments limiting claims 1, 55 and 63 to "about 37 degrees" were discussed. The undersigned pointed to the cited art and Applicant's previous submission which showed a teaching away from "about 37 degrees." The Examiner wished to see data showing unexpected results. No agreement with respect to the claims was reached.

Claim Rejections - 35 U.S.C. § 103 (a)

Claims 1-5, 7-19, 24, 55-57 and 59 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Newton et al (U.S. Patent No. 5,595,890) in view of Walker et al (Nucleic Acids Research, 1992, 20(7):1691-1696) and Krausa et al. (Human Immunology, 1995, 44:35-42).

An obviousness rejection may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997) In the present case, the cited art teaches away from currently amended independent claims 1, 55 and 63, which recite "under isothermal conditions at about 37 degrees Celsius." Newton et al. and Walker teach away from presently claimed use of isothermal conditions at low temperatures, because such conditions are likely to lead to the generation of artefactual products arising from extension of the detector primer even in the presence of a mismatched diagnostic nucleotide (for more detailed argument, please see the Request for Continued Examination submitted January 29, 2003). Accordingly, one of ordinary skill in the art would not have been motivated to combine the methods of Newton et al. and Walker et al. because the expectation of success resulting from this combination would have been low, and Krausa et al. adds no further relevant teachings. Indeed, the unexpected success of the claimed invention is set forth in Examples 1 and 2.

Further, because the prior art teaches away from a method "under isothermal conditions at about 37 degrees Celsius," the present claims do not represent an optimization of experimental conditions. One of ordinary skill in the art would have been motivated to increase, not decrease the temperature.

Accordingly, Applicants respectfully submit that the present claims are not obvious to one of ordinary skill in the art.

Applicants respectfully submit that Applicant's argument regarding isothermal conditions at low temperatures are commensurate with the scope of the present claims.

Claims 6 and 58 were rejected under 35 U.S.C §103(a) as being obvious over Newton et al. in view of Walker et al. and further in view of Reynolds (U.S. Patent No. 5,763,14) and Mullis et al. (U.S. Patent NO. 4,683,195).

Newton et al. and Walker et al. do not teach or suggest the claimed invention. Applicants respectfully submit that Reynolds and Mullis et al. are secondary references which add no further teachings which would enable one of ordinary skill in the art to achieve the claimed invention.

Claims 20, 21, 60 and 61 were rejected under 35 U.S.C §103(a).as being obvious over Newton et al. in view of Walker and further in view of Chen et al (Nucleic Acids Research, 1997, 25(2): 347-353).

For the same reasons provided above, Applicants respectfully submit that the additional teachings of the secondary reference Chen et al. do not enable one of ordinary skill in the art to achieve the claimed invention.

Claims 22 and 23 were rejected under 35 U.S.C §103(a).as being obvious over Newton et al. in view of Walker and further in view of Thomas et al. (U.S. Patent No. 6,025,130).

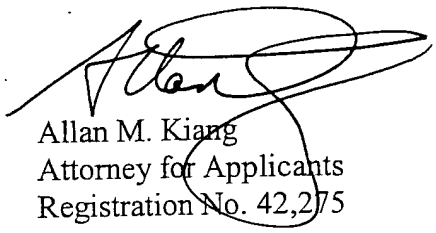
For the same reasons provided above, Applicants respectfully submit that the additional teachings of the secondary reference Thomas et al. would not enable one of ordinary skill in the art to achieve the claimed invention.

Accordingly, Applicants respectfully request withdrawal of the present rejections under Section 103.

Conclusion

The claims of the present application are believed to be in condition for allowance, and early notice thereof is respectfully requested.

Respectfully submitted,



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